DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 29 June 2009 and 29 July 2009.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 10-21, 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach the use of a single catheter performs the task of 1) deploying an annuloplasty ring, 2) grasping valve leaflets, and 3) clip applier a clip/staple onto the valve leaflets. Although Applicant shows that the leaflets can be grasped and clipped with a single device, for example with the device of Figure 63, Applicant does not show combining the grapser and clip applier with an annuloplasty device. Although Applicant argued in the response

filed 21 August 2007 that paragraph [0190] of the specification discloses combining the techniques, paragraph [0190] only contains a general statement that the device can be combined and Applicant does not provide any disclosure for what devices are combined and how they are combined.

Claims 1-5, 10-21, 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Independent claims 1, 11, 22 and 27 recite that a first structure/annuloplasty ring is deployed on a valve annulus in combination with deployment of second structure/staple on the valve leaflets using a catheter that has the ability to perform both operations without leaving the body between deployments. Although this is disclosed in the specification, as argued by Applicant in the response filed 21 August 2007, the specification merely states that such tools can be used together. No specific embodiment is disclosed in which the two devices are combined together on a single catheter. The disclosed embodiments each perform a single task. There is no specific description or figures of a method in which these two devices are used together. The specification only contains a general statement in the brief summary of the invention portion of the specification that these devices can be used together. In light of this, it would not be clear to a person of ordinary skill in the art how these devices are combined or used to modify the heart valve of a patient.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the catheter that deploys the annuloplasty device, grasps of the valve leaflets and fastens the valve leaflets together must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-29 and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keuhn et al. (US Patent 6,165,183) in view of Garrison et al. (US Patent 5,972,030) in view of Roth et al. (US Patent 5,823,956).

Claim 27, 28, 29, 31, 32: Kuehn'183 teaches a method of modifying a heart valve in patient that includes advancing a catheter through the vasculature (column 5, lines 38-42; column 13, lines 19-36) and use graspers (402; Figure 17) on the catheter to grasp the valve leaflets (column 8, line 59 to column 9, line 4) and then using a device (404) located on the same shaft (406) to deploy a clip (shown in Figure 17 but unlabeled) for the purpose of reducing regurgitation in a valve (column 1, lines 4-8). Kuehn'183 teaches combining more than one tool on the same catheter shaft (Kuehn'183 column 6, lines 34-44). Kuehn'183 teaches performing the procedure while the heart is still beating (column 12, lines 28-30).

Kuehn'183 does not teach deploying an annuloplasty device from the first catheter.

Garrison'030 teaches that it is old and well known to deploy an annuloplasty ring in combination with other valve repair techniques in order to maintain the contracted size of the valve (column 1, lines 58 to column 2, lines 6). Garrison'030 teaches that it is preferred to deploy the annuloplasty ring in a less invasive procedure that is through the vasculature and remote from the heart in order to reduce the amount of trauma

experienced by the patient (column 3, lines 6-23). Garrison'030 teaches that it is known to place annuloplasty rings on the entirely on the atrial side of the annulus (column 31, lines 26-51; also shown in Figure 44). It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kuehn'183 by also deploying an annuloplasty ring during the heart valve repair procedure in order to maintain the shape of the repaired valve.

Kuehn'183 in view of Garrison'030 does not teach deploying the annuloplasty ring while the heart is still beating.

Roth'956 teaches a less invasive method of accessing the heart that is similar to method taught by Garrison'030. Roth'956 teaches that it is preferable to keep the heart beating to avoid the trauma and risks associated with cardioplegic arrest. Roth'956 teaches performing valve repair procedures on the heart using this procedure (column 31, lines 30-65). It would be obvious to perform the method of Kuehn'183 in view of Garrison'030 while the heart is still beating, given the teachings and advantages disclosed by Roth'956.

Claim 33, 34, 35: Kuehn'183 teaches that the spatial relationship between the valve leaflets is changed by attaching opposed points on the valve leaflets together (Deployment of the clip on leaflets is not shown for the cited embodiment, however, the embodiment of Figure 13 shows that the spatial relationship between two leaflets is changed. See Figures 13a-13e). Regarding Claims 14-16 and 34-35, chordae and papillary muscles are part of the leaflets, therefore, opposed chordae and papillary muscles are linked when opposed leaflets are attached, as taught by Kuehn'183.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734